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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Anthony Nicolas Kalloo

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04/28/2004

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,336

Applicant(s)

Hallow et al

Examiner

J. Shay

Group Art Unit

3737

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on December 11, 2003
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) ~~1-19, 21, 22, 36~~ 1-19, 21, 22, 36 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-19, 21, 22 is/are rejected.
- ☒ Claim(s) 36 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 7, 12-15, 21 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mizuno et al.

See Figure 37 A and B and column 26, line 35 to column 7 line 39, inherently the incision in the wall would be closed in some manner so that digestive fluids would not leak into and damage the tissues of the peritoneum.

Claims 1 and 3 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Mizuno et al in combination with Inoue. Mizuno et al teach a method as claimed except for the express teaching of dilating the incision. Inoue teaches a method of dilating an incision. It would have been obvious to the artisan of ordinary skill to dilate the incision, since this would allow the sealing of Mizuno without requiring the excision of healthy tissue, thus producing a method such as claimed.

Claims 1, 4, and 5 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Mizuno et al in combination with Vander Salm et al. Mizuno et al teach a method such as claimed except insufflation of the peritoneal cavity. Vander Salm et al teach the desirability of insufflating the peritoneal cavity during endoscopic surgery. It would have been obvious to the artisan of ordinary skill to employ insufflation in the endoscopic procedure since this provides a working space, thus producing a method such as claimed.

Claims 1 and 6 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Mizuno et al in combination with Shermeta. Mizuno et al teach a method such as claimed except for the balloon inflation. Shermeta teach the use of a dual balloon fixation method for devices inserted

through the stomach wall. It would have been obvious to the artisan of ordinary skill to employ the dual balloon fixation method of Shermeta, in the method of Mizuno et al, since this would enable the endoscopic device to be fixed while the laproscopic instrument is manipulated into position, thus producing a method such as claimed.

Claim 1, and 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizuno et al in combination with Wilson-Cook Brochure. Mizuno et al teach a method such as claimed except for the needle knife and organ removal. Wilson-Cook Brochure teaches the use of a retractable needle knife in an endoscopic surgical procedure. It would have been obvious to the artisan of ordinary skill to employ a retractable needle knife in the method of Mizuno et al since this would enable the removal of bile stones and further to remove an organ e.g. the gall bladder since this is sometimes necessitated when stone removal is intended thus producing a method such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mizuno et al in combination with Wilson-Cook Brochure as applied to claims 1 and 7-18 above, and further in view of Bard Brochure. Bard Brochure teaches the use of a balloon dilator for a billiary procedure. It would have been obvious to the artisan of ordinary skill to include a dilation balloon on the needle knife of Wilson-Cook Brochure, since this would enable the passage to be dilated and thus facilitate the insertion of the needle knife, thus producing a method such as claimed.

Applicant argues that the method of Mizuno et al does not advance a flexible conduit. The examiner must respectfully disagree. Applicants attention is respectfully invited to the paragraph spanning columns 4 and 5 of the Mizuno et al reference which states, in pertinent part

“the surgical means comprises a surgical section which is connected to a distal end of the insertion section and which is able to bend to treat an affected part of the subject and/or provide an image of the affected part.” This is also shown e.g. in figure 38 wherein element 309 is discussed as a “bending tube” in the previously cited text at columns 26 and 27. The examiner also respectfully points out the ultimate sentence of column 26, which specifically states that the endoscopes may be inserted using a manipulator. Thus clearly the endoscope is inserted through a flexible conduit - the manipulator - and advanced to the portion of the wall to be excised. Applicant argues that the anchoring in Mizuno et al occurs prior to the incision. This argument is not well founded for two reasons. Firstly the argument is based on a limitation not found in the claim; there is no recitation of the temporal order in which the steps occur. Secondly there is no recitation in Mizuno et al of releasing the wall prior to the incising thereof. Thus once the incising has commenced, the anchoring of the conduit will still be occurring.

Applicant argues that it would have been unobvious to dilate any incision made by Mizuno et al. The examiner must respectfully disagree. As is well known in the art and shown in figure 37 A of Mizuno et al, frequently when a surface lesion manifests, the full peripheral extent of the lesion is not visible from the surface being treated. Thus dilating, insufflating and inspecting the outer wall of the organ, especially when removing cancerous lesions, is not merely obvious, but a necessity.

The arguments drawn to claims 7-20 are predicated in the presumed deficiencies of Mizuno et al as applied to claims 1-6 and are not convincing for the same reasons.

Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed December 11, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

Shay/DI

April 1, 2004



**DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330**